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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

STAICOVICI, STEFAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1732

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/774,470

Applicant(s)

PETERSON, ERIC D.

Examiner

Stefan Staicovici

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-7 and 16 in Paper No. 5 is acknowledged.

Claims 17-18 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Response to Amendment

2. Applicant's preliminary amendment filed January 30, 2001 has been entered. Claims 8-15 have been canceled. Claims 1 and 3-4 have been amended. Claims 1-7 and 16-18 are pending in the instant application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

✓ 4. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 16, lines 12-13, the limitation of a "nondeformed section...*in contact* with the surface of the metallic tubular member" (emphasis added) does not appear to

have support in the original disclosure. As can be seen in Figure 6, an annular gap exists in the nondeformed section between the metallic member (16) and the polymeric member (27).

✓ 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

✓ 6. Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the junction" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the polymeric collar" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gharibadeh (US Patent No. 5,108,525).

Gharibadeh ('525) teaches the claimed process of making an intravascular catheter by bonding a polymeric member (11) to a metallic member (12) in a leak-free (fluid tight) relationship (see col. 3, lines 60-63) including, mounting said polymeric member (11) against said metallic member (12), twisting and heating said polymeric member (11) against said metallic member (12) at a temperature between the transition (glass transition) temperature and the melting temperature of said polymeric member (11) (see col. 3, lines 64-67) such as to form a deformed portion (13) and a non-deformed portion adjacent to said deformed portion (see Figure 4). It is submitted that the twisting in combination with the heat shrinking creates a hot pressing action such as to form a "hot-pressed" bond.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-4, 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graver, Sr. (US Patent No. 4,390,668) in view of Sirhan *et al.* (US Patent No. 5,743,875).

Garver, Sr. ('875) teaches the basic claimed process bonding a polymeric member (20) to a metallic member (12) in a fluid-tight relationship (see col. 8, lines 15-19) including, mounting said polymeric member (20) against said metallic member (12) and further mounting an elastomeric member (24) over said polymeric (20) and metallic (12) members to form an

assembly, positioning said assembly in an electromagnetic heating unit (28), heating said metallic member (12) by electromagnetic heating such that the heat generated brings the temperature of the polymeric member (20) to the softening temperature (see col. 4, lines 50-57) and applying pressure by constricting said elastomeric member (24) about said polymeric (20) and metallic (12) such as to bond said polymeric member (20) to said metallic member (12) in a fluid-tight relationship and form a bonding area adjacent a non-bonded area (see Figure 2 and 3). It is submitted that the softening temperature of a thermoplastic material is a temperature between the glass transition temperature and the melting temperature of said thermoplastic material.

Regarding claims 1 and 16, Garver, Sr. ('875) does not teach an intravascular catheter. Sirhan *et al.* ('875) teach an intravascular catheter having a bonded outer tubular polymeric member (32) to a metallic member (51) (see col. 6, lines 20-28 and col. 9, lines 48-57, and Figure 6). Therefore, it would have been obvious for one of ordinary skill in the art to have made an intravascular catheter as taught by Sirhan *et al.* ('875) by using the process of Garver, Sr. ('875) because, Sirhan *et al.* ('875) specifically teach that an intravascular catheter requires a process of bonding a metallic member to a polymeric member, whereas Garver, Sr. ('875) teaches a process of making a bond between a metallic and a polymeric member and also because, both references teach similar materials and solve a similar problem of bonding a metallic member to a polymeric member.

In regard to claim 2, Garver, Sr. ('875) teaches that said polymeric member (20) includes an interior lumen (22) extending therethrough and at least a part of said metallic member (12) is

disposed within said lumen (22). Further, Garver, Sr. ('875) teaches pressing said polymeric member (20) against said metallic member (12) by constricting said elastomeric member (24) (see col. 4, lines 50-58).

Specifically regarding claim 4, Garver, Sr. ('875) teaches that elastomeric member (24) can be made from a plasticized vinyl material (see col. 5, lines 31-33). It is submitted that a vinyl material is a heat shrinking material (*i.e.*, PVC).

Regarding claim 3, Sirhan *et al.* ('875) teach an intravascular catheter having a PEEK polymeric member as an alternative to a polyester polymeric member (see col. 9, lines 49-55). Therefore, it would have been obvious for one of ordinary skill in the art to have made a PEEK intravascular catheter as taught by Sirhan *et al.* ('875) by using the process of Garver, Sr. ('875) because, Sirhan *et al.* ('875) specifically teach that a PEEK intravascular catheter requires a process of bonding a metallic member to a polymeric member, whereas Garver, Sr. ('875) teaches a process of making a bond between a metallic and a polymeric member and also because, both references teach similar materials and solve a similar problem of bonding a metallic member to a polymeric member. Further, it should be noted that Sirhan *et al.* ('875) specifically teach that a PEEK/metallic bond is an equivalent alternative to a polyester/metallic bond, whereas Garver, Sr. ('875) teaches a polyester/metallic bond.

In regard to claim 6, Garver, Sr. ('875) teaches a collar (24) (see Figure 2).

11. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graver, Sr. (US Patent No. 4,390,668) in view of Sirhan *et al.* (US Patent No. 5,743,875) and in further view of Riggs (US Patent No. 4,636,272).

Garver, Sr. ('875) in view of Sirhan *et al.* ('875) teach the basic claimed process as described above.

Regarding claims 5 and 7, although Garver, Sr. ('875) in view of Sirhan *et al.* ('875) teach a heat shrinking material, Garver, Sr. ('875) in view of Sirhan *et al.* ('875) do not specifically teach a fluoropolymer that is removed after bonding has occurred. Riggs ('272) teaches a process for bonding polymeric tubes (28, 34) including, using a Teflon (fluoropolymer) heat shrinking member (38) to apply pressure and removing said member after bonding has occurred. Therefore, it would have been obvious for one of ordinary skill in the art to have provided a Teflon (fluoropolymer) heat shrinking member (38) as taught by Riggs ('272) to increase the bonding pressure in the process of Garver, Sr. ('875) in view of Sirhan *et al.* ('875) because, Riggs ('272) specifically teaches that a Teflon (fluoropolymer) heat shrinking member is to be used to apply pressure when bonding dissimilar materials and can be removed after bonding, also because both Garver, Sr. ('875) and Riggs ('272) teach electromagnetic bonding, hence teaching similar processes.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (703) 305-

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0396. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:30 PM and alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan H. Silbaugh, can be reached at (703) 308-3829. The fax phone number for this Group is (703) 305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Stefan Staicovici, PhD



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August 11, 2002